



May 1, 2006

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Division of Dockets Management
(HFA-305)
Food and Drug Administration
Room 1061
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[Docket No. 1998P-0724, formerly 98P-0724] Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration
71 Federal Register 4839, January 30, 2006.

Dear Sir or Madam:

The Food Products Association (FPA) submits the following comments on the dockets referenced above.

FPA is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

With respect to the labeling of foods, FPA does not object to FDA's proposed rule, which would amend the color additive regulation governing carmine and cochineal extract (21 CFR 73.100), and would make a conforming amendment to the general rule governing the labeling of colors used in foods (21 CFR 101.22(k)), in order to require the declaration by name of these color additives. FPA concurs with FDA's tentative conclusion that the declaration of these color additives by name will provide sensitive consumers with the information they will need in order to avoid allergic reactions associated with the ingestion of these color additives.

While these color additives are used in a variety of foods, a number of food companies that use them are already declaring the color additives by name

in ingredient declarations. Declaration of these color additives by common or usual name, rather than by the class name “color,” is a permitted labeling approach under current FDA regulations.

Issues Related to Insect Derivation. FPA supports the decision by FDA not to require a statement about the insect derivation of these color additives on food labels. FPA believes, however, that the FDA could put forward a stronger rationale for its denial of the petitioned request for a statement about insect derivation, and we encourage FDA to reinforce its decision in the final rule.

It goes without saying that information regarding the insect derivation of carmine and cochineal extract is readily accessible to any interested person, since the fact of insect derivation is part of the basic definition of the colors. FPA believes, however, that a statement of insect derivation is not necessary since it is not a material fact of the type that would be required to be declared on a label or in labeling, under section 201(n) of the Federal Food, Drug and Cosmetic Act. For the vast majority of consumers, there are no consequences from the use of carmine and cochineal extract, and for those consumers who are allergic to the color additives, and thereby would experience consequences of use, the declaration of the color additives by name would satisfy the requirement to disclose the material fact.

Numerous food ingredients and additives are derived from animals, including insects. FDA does not require a statement about insect derivation about any of those ingredients or additives, such as honey or shellac.

Effect of the Incidental Additive Exemption (21 CFR 101.100(a)). There may be circumstances where carmine or cochineal extract are present in a finished food by virtue of having been an ingredient in a component of that food. In many cases, the carmine or cochineal extract in the finished food would be present at a very low level and would have no technical or functional effect in the finished food (e.g., does not impart color to the finished food). In these cases, FPA believes that carried-over levels of carmine or cochineal extract may benefit from the incidental additives exemption (21 CFR 101.100(a)) with respect to the ingredient labeling of the finished food. FPA notes that carmine and cochineal extract are not defined as major food allergens, and thus, in this case, the incidental additives exemption for such foods would not be in conflict with section 403(w)(4) of the Federal Food, Drug, and Cosmetic Act. FPA requests that FDA clarify this point in the preamble to the final rule on declaration of carmine and cochineal extract.

Proposed effective date. In its proposal, FDA notes that the effective date of any final rule would be two years from the date of publication of the final rule. FDA did not associate this rulemaking with its system of Uniform Effective Dates for food labeling regulations. The scope of the proposal extends beyond the labeling of food, yet it does propose an amendment to a food labeling regulation (21 CFR 101.22(k)). Because of this, FPA believes that FDA should give further consideration to its food labeling effective date system for any final rule on the declaration of carmine and cochineal extract.

We have noted that a number of FPA members that use these color additives already declare them by name on food labels and in labeling. There are some food companies, however, that may be declaring the additives by the class name "color." These companies would be required to change their labels when the final rule is published. FPA believes that FDA should establish the effective date of the carmine – cochineal extract labeling final rule as the Uniform Effective Date for food labeling, in order to allow those companies to coordinate the color declaration label change with any other label changes that may be needed at the time the final rule is published. Associating the color declaration effective date with the Uniform Effective Date for food labeling would minimize the need for more frequent label changes, which is the stated purpose of the Uniform Effective Date. FPA would not object to a bifurcated effective date, setting the effective date for the labeling of carmine and cochineal extract in foods as the Uniform Effective Date for food labeling, provided that foods are not penalized for this approach, and receive no less than two years as a compliance period for any color declaration final rule.

Thank you for the opportunity to comment on this important issue.

Sincerely,

A handwritten signature in cursive script, reading "Regina Hildwine".

Regina Hildwine
Senior Director,
Food Labeling and Standards
Food Products Association